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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/932,058 | 08/16/2001 | Jan Skouv | 49168-C (71994) | 5346 |

21874 7590 09/09/2003
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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|------------------------------|--|
| Office Action Summary | Application No. 09/932,058 | Applicant(s) SKOUV ET AL. | |
| | Examiner Jeffrey Fredman | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 49-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Wengel et al (WO 99/14226 (25 March 1999)).

Wengel teaches kits (see page 66, lines 1-15) which comprise reagents used in the methods shown such as example 160 where the reagents comprise

(a) an appropriate amount of nucleoside triphosphates (see page 182, line 7, also see page 165, example 48, line 18)

(b) an agent for polymerization (specifically AMV reverse transcriptase (see page 182, line 9 and page 165, line 19) as well as a substrate for ligases (see page 4, line 1),

(c) a primer which contains at least one LNA (see page 181, lines 15-30)

(d) a downstream primer (see page 165, example 148).

As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." It is clear that a structural difference must exist between the claimed invention and the prior art to overcome the rejection and not simply a

difference in the intended use. As MPEP 2111.02 also notes "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Here, there are no structural aspects which distinguish a primer of the claim from any other primer, since it is template dependent, not primer dependent.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backman et al (U.S. Patent 5,792,607) in view of Singh et al (Chem. Communications (February 1998) 455-456).

Backman teaches kits (see columns 29 and 30, claims 25-30) which comprise
(a) an appropriate amount of nucleoside triphosphates (see column 3, lines 35-40)

(b) an agent for polymerization (see column 30, claim 29) ,

(c) a pair of oligonucleotide primers (see column 29, claim 25)

(d) a ligase (see column 30, claim 30).

Backman does not teach incorporation of a LNA into the oligonucleotide primers.

Singh teaches the use of LNA based oligonucleotides in hybridization detection assays and suggests that these backbones have improved thermal stabilities and improved selectivities (abstract and page 456, table 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the kit of Backman with the use of LNA primers as taught by Singh since Singh states that "In this report it has been demonstrated that preorganized LNAs display 3' exonucleolytic stability and excellent ability to recognize complementary DNA and RNA. These results should make LNA a prime candidate for development of oligonucleotide based therapeutics and diagnostic probes, and LNA mediated nucleic acid recognition a novel concept of general applicability (Page 456, column 1)". An ordinary practitioner would have been motivated to combine the kit components of Backman with the use of LNA probes for

the express motivations of good 3' stability as well as their excellent ability to recognize complementary DNA and their increased thermal stabilities and improved selectivities (see abstract).

With regard to the secondary consideration of unexpected results which overcame the prima facie case of obviousness on the parent application 09/528,115, it is noted that MPEP 716.02(d) notes "the objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." Here, the claims are far broader than the evidence of nonobviousness. Because every primer can have a template which meets the mismatch requirements of the claims, the claims read on any kit for any method in which there is an LNA primer, dNTPs and a polymerase. This would literally cover PCR using LNA primers, which is prima facie obvious. The claim is not commensurate in scope with the secondary consideration of unexpected results because the unexpected results are limited to the mismatch assay claimed in the parent application while the kit claims would cover kits used in a variety of other assays.

Response to Arguments

6. Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive.

Applicant argues that the cited references do not teach particular elements of the claims, such as a Q' nucleic acid which differs from a Q nucleic acid by at least one position A. First, this argument entirely fails to read the claims with the appropriate breadth. Since Q' can be any nucleic acid and can differ from Q by any number of

positions, Q' and Q simply represent two different nucleic acids. No other limitation is present in this recitation. Both Wengel and Backman teach targeting nucleic acids for detection and therefore meet this claim limitation. Second, the limitation cited is entirely in the preamble and as noted above, since the limitation has no structural impact on the kit, it is disregarded. Further, Wengel and Backman teach all of the actual structural limitations of the claims.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1634